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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,546	12/23/2003	Gaku Ehara	031350	5792

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ARMSTRONG, KRATZ, QUINTOS, HANSON & BROOKS, LLP
1725 K STREET, NW
SUITE 1000
WASHINGTON, DC 20006

EXAMINER

TONGUE, LAKIA J

ART UNIT PAPER NUMBER

1645

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/743,546

Applicant(s)

EHARA ET AL.

Examiner

Lakia J. Tongue

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required, if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on May 13, 2005 is acknowledged. Claims 1-6 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Rejections Maintained

1. The rejection of claims 1-6 under 35 U.S.C. 103(a) as being obvious over Ehara, T. et al (JP 2002-355030) is maintained for the reasons set forth in the previous Office Action on page 2.

The rejection was on the grounds that Ehara et al discloses an invention that relates to the manufacture approach of sporangium containing the spore and the Pallas PORARU body of bacillus POPIRIE that has the prevention effectiveness to the Scarabaeidae insect by cultivating the bacillus belonging to bacillus POPIRIE (Bacillus popilliae, 0011) by the culture medium (0001).

The instant application teaches examples of components contained in such known liquid media including nitrogen sources, carbon sources and inorganic salts. Examples of nitrogen sources include inorganic nitrogen sources normally used for culturing microorganisms such as ammonia, nitric acid and salts thereof, and organic nitrogen sources such as peptones, meat extract, fish extracts, lactalbumin hydrolyzates and yeast extract (page 8-9 of the instant application). Ehara et al disclose that it is desirable that the nitrogen source needed for usual microbial cultivation besides glutamic acid is added by the culture medium used for the invention. As a nitrogen source, sources of organic nitrogen, such as the peptone and meat extract which are used for culture of a microorganism, fish meat extracts, a lactalbumin hydrolyzate, or yeast extract are usually mentioned. As the other nitrogen source, sources of inorganic nitrogen, Ehara et al disclose a desirable mass below 5% and since the concentration in the culture medium of the nitrogen source used for this invention presents the growth effect of the more desirable bacillus is 0.2-4.0 mass % (0019).

Additionally, Ehara et al, disclose the addition of glutamic acid as an effective prevention for the Scarabaeidae insect. This is characterized by cultivating the included

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culture medium for 0.2 to 4.0 mass % and an adsorbent (0009). Ehara et al, further discloses that the rate of glutamic acid to all the amino acid in a culture medium has a desirable mass of 35-90 % (0020). Ehara et al, also disclose that adding pyruvic acid to the culture medium is an excellent way to increase the growth sporangia (0024). The concentration of a pyruvic acid is 0.01 to 0.5 mass % (0025). Ehara et al disclose that there are 16 kinds of isolation mold amino acids that serve as a nitrogen source, they consists of alanine, arginine, aspartic acid, glutamic acid, glycine, isoleucine, leucine, lysine, methionine, phenylalamine, proline, serine, threonine, histidine, thyrosin and valine (0021). The Examiner interprets this section of the prior art to imply that that as glutamic acid, as is proline and the other 14 amino acids, are a source of nitrogen. Since the above mentioned amino acids are of the same source it would be possible to use the same weight needed for glutamic acid for proline. Ehara et al disclose the culture medium used for the manufacture approach of this invention may be a liquid or may be a solid medium (0026).

Lastly, Ehara et al, discloses a strain, which shows growth inhibition or insect-killing activity to the larva of the Scarabaeidae insect. The prior art discloses other strains belonging to *Bacillus popilliae*, including *popilliae Semadara*, *Bacillus popilliae var. popilliae*, *Bacillus popilliae var. popilliae hime* and *Bacillus popilliae var. popilliae sakura* etc. are mentioned (0032).

Applicant urges that a) the medium does not meet the limitations of "0.1 to 0.7% by weight of proline" recited in claim 1 and b) there is no suggestion in the reference for the proline limitation recited in the claim 1.

It is the Examiner's position that the claims are drawn to a process for producing sporangia of *Bacillus popilliae* containing spores and parasporal bodies by culturing *Bacillus popilliae* in a liquid medium containing an adsorbent and 0.1-0.7% by weight of proline. The prior art discloses that the invention offers glutamic acid in a culture medium by weight of 0.2 to 4.0 mass % (0009). Ehara et al, further discloses that the rate of glutamic acid to all the amino acid in a culture medium has a desirable mass of 35-90 % (0020). The prior art suggest that the there are 16 kinds amino acid which serve as a nitrogen source used for usual culture mediums. It is taught that the nitrogen source can come from alanine, arginine, aspartic acid, glutamic acid, glycine,

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isoleucine, leucine, lysine, methionine, phenylalamine, proline, serine, threonine, histidine, thyrosin and valine (0021). As submitted in the previous office action, the Examiner interprets this section of the prior art to imply that glutamic acid as is proline and the other 14 amino acids are sources of nitrogen. Since the above mentioned amino acids are of the same source it would be possible to use the same weight needed for glutamic acid for proline. Further more, the prior art teaches a weight less than 5.0 mass%, preferably 0.2 to 4.0 mass % of a nitrogen source. Thus, the teachings of less than 5.0 mass %, preferably 0.2 to 4.0 mass % would meet the limitation of claim 1. In addition, characteristics such as dosage would be a matter of optimization of experimental design parameters. Moreover, there is nothing on the record to show (via a side-by-side comparison) that the use of proline in place of glutamic acid would not be effective in the process of producing sporangia of *Bacillus popilliae*.

New Ground of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are indefinite because they do not recite

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positive active method steps. The claims do not recite a step where one actually collects or harvest sporangia. Additionally, the claims should recite "a process for producing sporangia of *Bacillus popilliae* containing spores and parasporal bodies comprising culturing *Bacillus popilliae* in a liquid medium containing an adsorbent and 0.1-0.7% by weight of proline.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 2005/0123518 A1. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim a process for producing sporangia of *Bacillus popilliae* containing spores and parasporal bodies by culturing *Bacillus popilliae* in a liquid medium containing an adsorbent and 0.1-0.7% by weight of sources of nitrogen. The copending application disclose that there are 16

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types of free amino acids (alanine, arginine, aspartic acid, glutamic acid, glycine, isoleucine, leucine, lysine, methionine, phenylalamine, proline, serine, threonine, histidine, thyrosin and valine) that are known to be contained in nitrogen sources, which are ordinarily found in culture media (0029). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to substitute one amino acid for another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion


4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


LJT


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600